

REMARKS

Status of the Claims

Claims 24-59 are currently pending. Claims 1-23 have been canceled without prejudice or disclaimer of the subject matter claimed therein. Claims 28, 33, 36-53, and 55-59 have been withdrawn from examination. Claims 24-27, 29-32, 34, 35, and 54 are currently under examination.

Amendments to the Claims

Claims 24 and 54 have been amended.

Claim 24 has been amended to replace the phrase “substantially” with the phrase “virtually.” Representative support for the amendment can be found at page 17, line 25 of the specification.

Claim 54 has been amended. Representative support for the amendment can be found in claim 54 as filed.

The amendments to the claims do not add prohibited new matter.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 24-27, 29-32, 34, 35, and 54 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The Office Action alleges that the phrase “substantially free” renders the claim indefinite. Without acquiescing to the merits of the rejection, Applicants have amended the claim to recite that the composition is “virtually free.” It is submitted that representative support for this phrase can be found in the specification at page 17, line 25. It is further submitted that the specification defines this term, thereby making its usage clear and definite.

The Office Action further alleges that the claims are indefinite for recitation of the phrase “at least about.” Without acquiescing to the merits of this rejection, claim 24 has been amended to delete the word “about.”

The Office Action alleges that claim 54 is indefinite for reciting the phrase “pharmaceutically effective amount.” Without acquiescing to the merits of this rejection, claim 54 has been amended to delete the phrase “pharmaceutically effective amount.”

Rejection Under 35 U.S.C. § 102(b)

Claims 24 and 54 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wall (U.S. Patent 4,981,968).

The Office Action alleges that Wall discloses water soluble camptothecin analogs with a free carboxyl group comprising an organic cation. However, Wall discloses camptothecin analogs comprising the lactone forms of camptothecin (see E-ring of formula depicted by Wall starting at column 4, line 3). The claims of the present application are directed to compositions comprising the carboxylate form of a camptothecin drug. As depicted in Figure 1 of the present application, the carboxylate form of a camptothecin drug contains a hydrolysed lactone ring (the E-ring is opened into the carboxylate form). Accordingly, the claimed composition is virtually free of the lactone form of camptothecin.

In contrast, Wall discloses compositions comprising camptothecin analogs having an intact lactone ring. The camptothecin analogs of Wall comprises a carboxyl group on the A ring and a lactone ring (E-ring). Thus, the compositions of Wall comprising the camptothecin analogs are not free of the lactone form of a camptothecin.

Therefore, the claimed composition is not disclosed or suggested by Wall. Applicants respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

A. Claims 25-27, 29, 31, 32, 34, 35, and 54 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over the cited reference of Wall (U.S. Patent 4,981,968) in view of Epstein (U.S. Patent 4,897,355).

The Office Action alleges that Wall discloses the features of claim 24, from which claims 25-27, 29, 31, 32, 34, 35 depend directly or in directly. The Office Action relies on Epstein to disclose the features of these dependent claims. However, as discussed above, Wall does not disclose the features of claims 24 or 54. Moreover, Epstein does not overcome the deficiencies

of Wall because Eppstein does not disclose compositions comprising the carboxylate form of camptothecin that is free of the lactone form. Eppstein only discloses compositions comprising cationic lipids. Accordingly, the cited references, when combined, do not render claims 25-27, 29, 31, 32, 34, 35, and 54 obvious. It is respectfully requested that this rejection be withdrawn.

B. Claims 24, 25, and 30 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over the cited reference of Wall (U.S. Patent 4,981,968) in view of Prakash (U.S. Patent 5,654,484).

The deficiencies of Wall are discussed above. Prakash does not overcome the deficiencies of Wall because Prakash does not disclose compositions comprising the carboxylate form of camptothecin that is free of the lactone form. Prakash only discloses polyamine derivatives for the treatment of neoplastic diseases. Accordingly, the cited references, when combined, do not render claims 24, 25, and 30 obvious.

U.S. Applications

Applicants respectfully provide the status of pending U.S. applications with the same assignee that may be considered to be technically related for the Examiner's consideration.

Application	Status
10/584,296	Pending
10/584,349	Pending

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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